**DEPARTMENT OF MANAGED HEALTH CARE**
**FINAL TEXT OF PROPOSED REGULATIONS**

**Independent Medical Review/ Grievance Systems**

*Amendment by repeal of section 1300.68, and adoption of section 1300.68*

~~§ 1300.68. Grievance System.~~

~~Every health care service plan shall establish a grievance system pursuant to the requirement of Section 1368 of the Act.~~

~~(a) The grievance system shall be established, pursuant to written procedures, for the receipt, handling and resolution of complaints within 30calendar days of receipt by the plan, or the entity contracted by the plan to administer its grievance system.~~

~~(b) The plan's grievance system shall include at least the following features.~~

~~(1) An officer of the plan shall be designated as having primary responsibility for the maintenance of such procedures and for the review of their operations and for the utilization of any emergent patterns of grievances in the formulation of policy changes and procedural improvements in the plan's administration whether or not the plan administers its own grievance system or delegates its authority to resolve grievances to another entity.~~

~~(2) At least one telephone number for the filing of complaints shall be located within each service area including facilities of providers which hare used by the plan. The locations for filing complaints and telephone numbers and related procedures regarding grievances shall be communicated in writing to enrollees and subscribers.~~

~~(3) As to each complaint received in person or by telephone at a grievance location, a written record shall be made, including the date, identification of the individual recording the grievance, and disposition. A written record of tabulated grievances shall be reviewed periodically by the governing body of the plan, the public policy body created pursuant to Section 1300.69, and by an officer of the plan or his designee, and the review procedure shall be documented, including documentation of the procedure or mechanism used in consideration of tabulating grievances periodically in relation to policy and procedure review.~~

~~(4) At each grievance location, assistance shall be provided in the filing of grievances. A "patient advocate" or ombudsperson may be used.~~

~~(5) Complaint forms and a copy of the grievance procedure shall be readily available at each facility of the plan and the plan shall provide them to subscribers and enrollees promptly upon request.~~

~~(6) The plan shall assure that there is no discrimination against an enrollee or subscriber (including cancellation of the contract) solely on the grounds that the enrollee filed a complaint.~~

~~(7) A grievance system shall provide (1) for the acknowledgement of the receipt of a complaint and notice to the complainant of who may be contacted with respect to the complaint within five (5) days, and (2) for notice and a written statement to the complainant of the disposition or pending status of the complaint within 30 days of the plan's receipt of the complaint. Where the plan is unable to distinguish between complaints and inquiries, they shall be considered complaints.~~

~~(8) A grievance system shall provide for a prompt review of complaints by the management or supervisory staff responsible for the services or operations which are the subject of the complaint.~~

~~(9) Copies of grievances and responses that the plan is required to maintain for five years, shall include a copy of all medical records, documents, evidence of coverage and other relevant information upon which the plan relied to reach its decision.~~

~~(10) The grievance system shall include procedures for the expedited review of grievances for cases involving imminent and serious threat to the health of the enrollee, and shall include the elements set forth in section 1300.68.01.~~

~~(c) Department review of grievances.~~

~~An enrollee may submit a grievance to the Department for review, after completing the plan's grievance process or after having participated in the plan's grievance system for 30 days; however, this requirement shall be waived if the Department determines that an earlier review is necessary (see section 1300.68.01). Upon receipt of such grievance, the Department shall notify the plan, and the plan shall submit within five (5)calendar days after receipt of the notification, the following information:~~

~~(1) The plan's response to the issues raised by the enrollee's grievance filed with the Department.~~

~~(2) A copy of the plan's response to the enrollee's grievance filed with the plan.~~

~~(3) A complete and legible copy of any and all medical records related to the grievance.~~

~~(4) A copy of the cover page of the applicable evidence of coverage and other relevant pages of the evidence of coverage with the specific sections pertaining to the enrollee's grievance underlined.~~

~~(5) Any other relevant information that the plan used to reach its decision.~~

~~(6) Any other information that the plan believes is relevant to the resolution of the grievance.~~

~~(7) If the plan did not use medical records or did not rely upon any information other than the evidence of coverage to make its decision, the plan shall so state in its response to the Department.~~

~~The Department may request additional information or medical records from the plan. Should additional information be requested, the plan shall submit this information within five (5) business days of receipt of the Department's request.~~

~~Any delay caused by the plan's failure to submit the requested information may result in the Department ruling in the enrollee's favor on any issue that the Department cannot decide without the information in question.~~

~~(d)(1) The quarterly report required by subdivision (c) of Section 1368of the Act shall include complaints filed by enrollees that are pending and unresolved for 30 days or more within the plan's grievance system. When a plan's grievance system provides one or more opportunities for appeal, an enrollee's complaint shall be included in the plan's quarterly report until the enrollee has exhausted all opportunities for appeal or the time for appeal under the grievance system has expired. The quarterly report shall not include complaints filed and/or processed outside the plan's grievance system in other complaint resolution procedures, such as arbitration, voluntary mediation, the Center for Health Care Dispute Resolution, an independent review organization, the Medi-Cal Fair Hearing Process or the Department of Managed Care.~~

(2) A plan that has no complaints within the plan's grievance system that are pending and unresolved for 30 days or more shall file the quarterly report required by subdivision (c) of Section 1368 of the Act notifying the Department of that fact.

(3) The quarterly report shall be prepared for the quarter ending on March 31st, June 30th, September 30th and December 31st of each calendar year, and shall include complaints pending and unresolved for 30days or more during the quarter. The quarterly report shall not contain personal or confidential information with respect to any enrollee.

(4) The quarterly report shall specify the licensee's name, quarter and date of the report, categories reported, type of grievance system based on levels of appeal, and a breakdown of the total number of pending and unresolved complaints for each category and for each level of the plan's grievance system. The breakdown shall include the number of complaints for each corresponding reason specified in the report. If complaints are pending and unresolved for reasons other than reasons specified in the quarterly report, those other reasons shall be specified in the report together with the corresponding number of complaints for each reason. If a grievance system provides two or more levels of appeal, each level shall be separately listed in the report and shall include the same information required by the report for First Level Appeals.

(5) The quarterly report shall be signed by a person authorized to do so by the plan, verified, and filed along with two copies of the quarterly report, in the Department's Sacramento Office to the attention of the Filing Clerk no later than 30 days from the close of the quarter. The quarterly report need not be filed as an amendment to the plan application.

(6) The quarterly report shall be filed in the format specified below:

STATE OF CALIFORNIA DEPARTMENT OF MANAGED CARE

QUARTERLY REPORT OF PENDING AND UNRESOLVED GRIEVANCES
PURSUANT TO HEALTH AND
SAFETY CODE SECTION 1368(c)

1. Name of Licensed Health Plan (as appearing on license):

_____

2. Report for Quarter Ending: _____

3. Categories of Complaints Included in this Report: (Include total plan enrollment for each category.)

Category Enrollment
( ) Commercial _____
( ) Medicare (Risk) _____
( ) Medicare (Supplement) _____
( ) Medi-Cal _____

4. Type of Grievance System Based on Levels of Appeal Allowed by Plan:

( ) Initial Complaint Only (No Appeal Allowed)

( ) One-Level Appeal (One Appeal Allowed)

( ) Two-Level Appeal (Two Appeals Allowed)

( ) Multi-Level Appeal (Three or More Appeals Allowed)

5. Breakdown of number of pending and unresolved complaints for each category and each level in the grievance system, as follows:

Category: _____

INITIAL COMPLAINTS

Number of Complaints Reasons
_____ Pending additional information from enrollee.
_____ Pending additional information from provider.
_____ Pending plan's review and determination.
Other Reason(s) (Specify):
_____ a. _____
_____ b. _____
_____ c. _____

_____ (Continue, if necessary)

_____ TOTAL INITIAL COMPLAINTS

FIRST-LEVEL APPEALS

Number of Complaints Reasons
_____ Pending receipt of any appeal filed by enrollee.
_____ Pending additional information from enrollee.
_____ Pending additional information from provider.
_____ Pending plan's review and determination.
Other Reason(s) (Specify):
_____ a. _____
_____ b. _____
_____ c. _____
(Continue, if necessary)

_____ TOTAL FIRST-LEVEL APPEALS
[NOTE: If the Grievance System provides two or more levels of appeal, each level shall be separately listed, and shall include the same information required by the report for First-Level Appeals.]

_____ TOTAL NUMBER OF COMPLAINTS FOR THIS CATEGORY
[NOTE: List breakdown for next category of complaints marked in Item 3. as set forth in Item 5.]

VERIFICATION

I, the undersigned, have read and signed this report and know the contents thereof, and verify that, to the best of my knowledge and belief, the information included in this report is true.

By: _____

(Signature of Individual Authorized to Sign on Behalf of the Plan.)

~~Name: _____~~

~~(Typed or Printed)~~

~~Title: _____~~

~~Note: Authority cited: Section 1344, Health and Safety Code. Reference: Section 1368, Health and Safety Code.~~

§ 1300.68. Grievance System.

Every health care service plan shall establish a grievance system pursuant to the requirements of Section 1368 of the Act.

(a) The grievance system shall be established in writing and provide for procedures that will receive, review and resolve grievances within 30 calendar days of receipt by the plan, or any provider or entity with delegated authority to administer and resolve the plan's grievance system. The following definitions shall apply with respect to the regulations relating to grievance systems:

(1) "Grievance" means a written or oral expression of dissatisfaction regarding the plan and/or provider, including quality of care concerns, and shall include a complaint, dispute, request for reconsideration or appeal made by an enrollee or the enrollee's representative. Where the plan is unable to distinguish between a grievance and an inquiry, it shall be considered a grievance.

(2) "Complaint" is the same as "grievance."

(3) "Complainant" is the same as "grievant," and means the person who filed the grievance including the enrollee, a representative designated by the enrollee, or other individual with authority to act on behalf of the enrollee.

(4) "Resolved" means that the grievance has reached a final conclusion with respect to the enrollee's submitted grievance, and there are no pending enrollee appeals within the plan's ~~internal~~ grievance system, including entities with delegated authority.

(A) If the plan has multiple internal levels of grievance resolution or appeal, all levels must be completed within 30 calendar days of the plan's receipt of the grievance.

(B) Grievances that are not resolved within 30 calendar days, or grievances referred to the Department's complaint or independent medical review system, shall be reported as "pending" grievances pursuant to subsection (f) below. Grievances referred to

external review processes, such as reviews of Medicare Managed Care determinations pursuant to 42 C.F.R. Part 422, or the Medi-Cal Fair Hearing process, shall also be reported pursuant to subsection (f) until the review and any required action by the plan resulting from the review is completed.

(b) The plan's grievance system shall include the following:

(1) An officer of the plan shall be designated as having primary responsibility for the plan's grievance system whether administered directly by the plan or delegated to another entity. The officer shall continuously review the operation of the grievance system to identify any
emergent patterns of grievances. The system shall include the reporting procedures in order to improve plan policies and procedures.

(2) Each plan's obligation for notifying subscribers and enrollees about the plan's grievance system shall include information on the plan's procedures for filing and resolving grievances, and the telephone number and address for presenting a grievance. The notice shall also include information regarding the Department's review process, the independent medical review system, and the Department's toll-free telephone number and website address.

(3) The grievance system shall address the linguistic and cultural needs of its enrollee population as well as the needs of enrollees with disabilities. The system shall ensure all enrollees have access to and can fully participate in the grievance system by providing assistance for those with limited English proficiency or with a visual or other communicative impairment. Such assistance shall include, but is not limited to, translations of grievance procedures, forms, and plan responses to grievances, as well as access to interpreters, telephone relay systems and other devices that aid disabled individuals to communicate. Plans shall develop and file with the Department a policy describing how they ensure that their grievance system complies with this subsection within 90 days of the effective date of this regulation.

(4) The plan shall maintain a toll-free number, or a local telephone number in each service area, for the filing of grievances.

(5) A written record shall be made for each grievance received by the plan, including the date received, the plan representative recording the grievance, a summary or other document describing ~~of~~ the grievance, and its disposition. The written record of grievances shall be reviewed periodically by the governing body of the plan, the public policy body created pursuant to section 1300.69, and by an officer of the plan or his designee. This review shall be thoroughly documented.

(6) The plan grievance system shall ensure that assistance in filing grievances shall be provided at each location where grievances may be submitted. A "patient advocate" or ombudsperson may be used.

(7) Grievance forms and a description of the grievance procedure shall be readily available at each facility of the plan, on the plan's website, and from each contracting provider's office or facility. Grievance forms shall be provided promptly upon request.

(8) The plan shall assure that there is no discrimination against an enrollee or subscriber (including cancellation of the contract) on the grounds that the complainant filed a grievance.

(9) The grievance system shall allow enrollees to file grievances for at least 180 calendar days following any incident or action that is the subject of the enrollee's dissatisfaction.

(c) Through periodic medical surveys under Section 1380 of the Act, the Department shall periodically review the plan's grievance system, including the records of grievances received by the plan, and assess the effectiveness of the plan policies and actions taken in response to grievances.

(d) The plan shall respond to grievances as follows:

(1) A grievance system shall provide for a written acknowledgment within five (5) calendar days of receipt, except as noted in subsection (d)(8). The acknowledgment will advise the complainant that the grievance has been received, the date of receipt, and provide the name of the plan representative, telephone number and address of the plan representative who may be contacted about the grievance.

(2) The grievance system shall provide for a prompt review of grievances by the management or supervisory staff responsible for the services or operations which are the subject of the grievance.

(3) The plan's resolution, containing a written response to the grievance shall be sent to the complainant within thirty (30) calendar days of receipt, except as noted in subsection (d)(8). The written response shall contain a clear and concise explanation of the plan's decision. Nothing in this regulation requires a plan to disclose information to the grievant that is otherwise confidential or privileged by law.

(4) For grievances involving delay, modification or denial of services based on a determination in whole or in part that the service is not medically necessary, the plan shall include in its written response, the reasons for its determination. The response shall clearly state the criteria, clinical guidelines or medical policies used in reaching the determination. The plan's response shall also advise the enrollee that the determination may be considered by the Department's independent medical review system. The response shall include an application for independent medical review and instructions, including the Department's toll-free telephone number for further information and an envelope addressed to the Department of Managed Health Care, HMO Help Center, 980 Ninth Street, 5th Floor, Sacramento, CA 95814.

(5) Plan responses to grievances involving a determination that the requested service is not a covered benefit shall specify the provision in the contract, evidence of coverage or member handbook that excludes the service. The response shall either identify the document and page where the provision is found, direct the grievant to the applicable section of the contract containing the provision, or provide a copy of the provision and explain in clear concise language how the exclusion applied to the specific health care service or benefit requested by the enrollee. In addition to the notice set forth at Section 1368.02(b) of the Act, the response shall also include a notice that if the enrollee believes the decision was denied on the grounds that it was not medically necessary, the Department should be contacted to determine whether the decision is eligible for an independent medical review.

(6) Copies of grievances and responses shall be maintained by the Plan for five years, and shall include a copy of all medical records, documents, evidence of coverage and other relevant information upon which the plan relied in reaching its decision.

(7) The Department's telephone number, the California Relay Service's telephone numbers, the plan's telephone number and the Department's Internet address shall be displayed in all of the plan's acknowledgments and responses to grievances in 12-point boldface type with the statement contained in subsection (b) of Section 1368.02 of the Act.

(8) Grievances received over the telephone that are not coverage disputes, disputed health care services involving medical necessity or experimental or investigational treatment, and that are resolved by the close of the next business day, are exempt from the requirement to send a written acknowledgment and response. The plan shall maintain a log of all such grievances containing the date of the call, the name of the complainant, member identification number, nature of the grievance, nature of resolution, and the plan representative's name who took the call and resolved the grievance. The information contained in this log shall be periodically reviewed by the plan as set forth in subsection (b).

(e) The plan's grievance system shall track and monitor grievances received by the plan, or any entity with delegated authority to receive or respond to grievances. The system shall:

(1) Monitor the number of grievances received and resolved; whether the grievance was resolved in favor of the enrollee or plan; and the number of grievances pending over 30 calendar days. The system shall track grievances under categories of Commercial, Medicare and Medi-Cal/other contracts. The system shall indicate whether an enrollee grievance is pending at: 1) the plan's internal grievance system; 2) the Department's consumer complaint process; 3) the Department's Independent Medical Review system; 4) an action filed or before a trial or appellate court; or 5) other dispute resolution process. Additionally, the system shall indicate whether an enrollee grievance has been submitted to: 1) the Medicare review and appeal system; 2) ~~3)~~ the Medi-Cal fair hearing process; or 3) arbitration.

(2) The system shall be able to indicate the total number of grievances received, pending and resolved in favor of the enrollee at all levels of grievance review and to describe the issue or issues raised in grievances as 1) coverage disputes, 2) disputes involving medical necessity, 3) complaints about the quality of care and 4) complaints about access to care

(including complaints about the waiting time for appointments), and 5) complaints about the quality of service, and 6) other issues.

(f) Quarterly Reports

(1) All plans shall submit a quarterly report to the Department describing grievances that were or are pending and unresolved for 30 days or more. The report shall be prepared for the quarters ending March 31st, June 30th, September 30th and December 31st of each calendar year. The report shall also contain the number of grievances referred to external review processes, such as reconsiderations of Medicare Managed Care determinations pursuant to 42 C.F.R. Part 422, the Medi-Cal fair hearing process, the Department's complaint or Independent Medical Review system, or other external dispute resolution systems, known to the plan as of the last day of each quarter.

(2) The quarterly report shall include:

(A) The licensee's name, quarter and date of the report;

(B) The total number of grievances filed by enrollees that were or are pending and unresolved for more than 30 calendar days at any time during the quarter under the categories of Commercial, Medicare, and Medi-Cal/other products offered by the plan;

(C) A brief explanation of why the grievance was not resolved in 30 days, and indicate whether the grievance was or is pending at: 1) the plan's internal grievance system; 2) the Department's consumer complaint process; 3) the Department's Independent Medical Review system; 4) court; or 5) other dispute resolution processes. Alternatively, the plan shall indicate whether the grievance was or is submitted to: 1) the Medicare review and appeal system; 2) the Medi-Cal fair hearing process; or 3) arbitration.

(D) The nature of the unresolved grievances as 1) coverage disputes; 2) disputes involving medical necessity; 3) complaints about the quality of care; 4) complaints about access to care (including complaints about the waiting time for appointments); 5) complaints about the quality of service; and 6) other issues. All issues reasonably described in the grievance shall be separately categorized.

(E) The quarterly report shall not contain personal or confidential information with respect to any enrollee.

(3) The quarterly report shall be verified by an officer authorized to act on behalf of the plan. The report shall be submitted in writing or through electronic filing to the Department's Sacramento Office to the attention of the Filing Clerk no later than 30 days after each quarter. The quarterly report shall not be filed as an amendment to the plan application.

(4) The quarterly report shall be filed in the format specified in subsection (i).

(g) An enrollee may submit a grievance to the Department. The Department shall notify the plan, and within five (5) calendar days after notification, the plan shall provide the following information to the Department:

(1) A written response to the issues raised by the grievance.

(2) A copy of the plan's original response sent to the enrollee regarding the grievance.

(3) A complete and legible copy of all medical records related to the grievance. The plan shall inform the Department if medical records were not used by the plan in resolving the grievance.

(4) A copy of the cover page and all relevant pages of the enrollee's Evidence of Coverage (EOC), with the specific applicable sections underlined. If the plan relied solely on the EOC, the plan shall notify the Department of that fact.

(5) All other information used by the plan or relevant to the resolution of the grievance.

(6) The Department may request additional information or medical records from the plan. Within five (5) calendar days of receipt of the Department's request, the plan shall forward information and records that are maintained by the plan or any contracting provider. If requested information cannot be timely forwarded to the Department, the plan's response will describe the actions being taken to obtain the information or records and when receipt is expected.

(h) Nothing in this section shall preclude an enrollee from seeking assistance directly from the Department in cases involving an imminent or serious threat to the health of the enrollee or where the Department determines an earlier review is warranted. In such cases, the Department may require the plan and contracting providers to expedite the delivery of information.

The Department may consider the failure of a plan to timely provide the requested information as evidence in favor of the enrollee's position in the Department's review of grievances submitted under subsection (b) of Section 1368 of the Act.

(i)

STATE OF CALIFORNIA
DEPARTMENT OF MANAGED HEALTH CARE
QUARTERLY REPORT OF
PENDING AND UNRESOLVED GRIEVANCES
PURSUANT TO HEALTH AND SAFETY CODE SECTION 1368(c)

Name of Licensed Health Plan (as appearing on license):

_____

DMHC Plan File No.: ___-_____
Report for _____Quarter 200 _____

Categories of Grievances Included in this Report: (Check and list current enrollment)
Commercial _____ Medicare _____ Medi-Cal _____
Healthy

Families

Under Medicare and Medi-Cal law, Medicare enrollees and Medi-Cal enrollees each have separate avenues that are not available to other enrollees. Therefore, grievances pending and unresolved may reflect enrollees pursuing their Medicare or Medi-Cal appeal rights.

I. Total Number of Grievances Unresolved Within 30 Days During the Quarter

Note: These include all grievances received by the plan or any entity to which the plan has delegated grievance resolution.

| | Total | Comm | Medi-care | Medi-Cal |
|---|---|---|---|---|
| A. Total number of grievances pending or submitted over 30 days at the beginning of the quarter | | | | |
| B. Total number of additional grievances which exceeded the 30 days timeframe for resolution during this quarter | | | | |
| C. Total number of grievances that were unresolved within 30 days at any time during quarter (A + B) | | | | |
| D. Total number of grievances pending or submitted over 30 days at the end of the quarter | | | | |

II. Commercial Members

Number of Commercial Member Grievances Unresolved Within 30 Days During the Quarter by Type of Grievance

| Reason Why Pending Over 30 Days | Total, all grievance types | Coverage Disputes | Disputes Involving Medical Necessity | Quality of Care | Access to Care (including appointments) | Quality of Service |
|---|---|---|---|---|---|---|
| 1. Pending in Plan's Internal Grievance System | | | | | | |
| 2. Pending in Department's consumer complaint process | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 3. Pending in Department's Independent Medical Review system | | | | | | |
| 4. Submitted to Arbitration | | | | | | |
| 5. Pending in Court | | | | | | |
| 6. Pending, other dispute resolution | | | | | | |
| Total | | | | | | |

III. Medicare Members (complete if Medicare + Choice products provided by Plan)

Number of Medicare Member Grievances Unresolved Within 30 Days During the Quarter by Type of Grievance

| Reason Why Pending Over 30 Days | Total, all grievance types | Coverage Disputes | Disputes Involving Medical Necessity | Quality of Care | Access to Care (including appointments) | Quality of Service |
|---|---|---|---|---|---|---|
| 1. Pending in Plan's Internal Grievance System | | | | | | |
| 2. Submitted to Medicare Appeals System | | | | | | |
| 3. Pending in Department's consumer complaint process | | | | | | |
| 4. Pending in Department's Independent Medical Review system | | | | | | |
| 5. Submitted to Arbitration | | | | | | |
| 6. Pending in Court | | | | | | |
| 7. Pending other dispute resolution | | | | | | |
| Total | | | | | | |

IV. Medi-Cal Members (Complete if Medi-Cal Managed Care products offered by Plan)

Number of Medi-Cal Member Grievances Unresolved Within 30 Days During the Quarter by Type of Grievance

| Reason Why Pending Over 30 Days | Total, all grievance types | Coverage Disputes | Disputes Involving Medical Necessity | Quality of Care | Access to Care (including appointments) | Quality of Service |
|---|---|---|---|---|---|---|
| 1. Pending in Plan's Internal Grievance System | | | | | | |
| 2. Submitted to Medi-Cal fair hearing process | | | | | | |
| 3. Pending in Department's consumer complaint process | | | | | | |
| 4. Pending in Department's Independent Medical Review system | | | | | | |
| 5. Submitted to Arbitration | | | | | | |
| 6. Pending in Court | | | | | | |
| 7. Pending, other dispute resolution | | | | | | |
| Total | | | | | | |

VERIFICATION

I, the undersigned, have read and signed this report and know the contents thereof, and verify that, to the best of my knowledge and belief, the information included in this report is true.

BY: _____
(Signature of Individual Authorized to Sign on Behalf of Plan)

(Typed Name, Title, Phone)

AUTHORITY:

Note: Authority cited: Section 1344, Health and Safety Code. Reference: Section 1368, Health and Safety Code.

*Amendment by repeal of section 1300.68.01, and adoption of section 1300.68.01*

~~§ 1300.68.01. Expedited Review of Grievances.~~

~~(a) Every plan shall include within its grievance system, procedures for the expedited review of grievances involving an imminent and serious threat to the health of the enrollee ( "urgent grievances"). At a minimum, plan procedures for urgent grievances shall include the following:~~

~~(1) The plan shall immediately notify the complainant of his/her right to notify the Department of the grievance.~~

~~(2) The plan shall provide the complainant and the Department with a written statement on the disposition or pending status of the urgent grievance within three (3) days of receipt.~~

~~(3) The enrollee's medical condition shall be considered when determining the response time.~~

~~(b) The plan shall establish a system that provides for receipt of Department contacts regarding urgent grievances twenty four hours a day, seven days a week. During normal business hours, the system shall provide for the plan to contact the Department within thirty (30) minutes following Department contacts regarding urgent grievances. After normal business hours, on weekends or holidays, the system shall provide for the plan to contact the Department within one (1) hour following Department contacts regarding urgent grievances.~~

~~The system established by the plan shall provide for the availability of a plan representative with authority on the plan's behalf to resolve urgent grievances and authorize the provision of health care services covered under the enrollee's plan contract in a medically appropriate and timely manner. Such authority shall include making financial decisions for expenditure of funds on behalf of the plan without first having to obtain approval from supervisors or other superiors within the plan. Nothing in this subsection shall restrict the plan representative from consulting with other plan staff on urgent grievances.~~

~~(c) Plans shall provide the Department with the following information with respect to plan procedures for urgent grievances:~~

~~(1) A description of the system established by the plan pursuant to subsection (b).~~

~~(2) The description shall include the system's provisions for scheduling qualified plan representatives, including back-up plan representatives as necessary, to be available twenty-four (24) hours a day, seven days a week to respond to Department contacts regarding urgent grievance representatives. Provisions for scheduling shall include the names and titles of those plan representatives who will be available under the system, their telephone numbers, and, as applicable, pager numbers, answer service numbers, voice-mail numbers, e-mail addresses, or other means for contact.~~

~~(3) The description shall provide the Department with information on how to access the system established by the plan.~~

~~(4) If the plan revises the system established pursuant to subsection (b), the plan shall notify the Department at least thirty (30) days in advance of implementing the revisions.~~

~~Note: Authority cited: Section 1344, Health and Safety Code. Reference: Sections 1368 and 1368.01, Health and Safety Code~~

1300.68.01. Expedited Review of Grievances.

(a) Every plan shall include in its grievance system, procedures for the expedited review of grievances involving an imminent and serious threat to the health of the enrollee, including, but not limited to, severe pain, potential loss of life, limb or major bodily function ("urgent grievances"). At a minimum, plan procedures for urgent grievances shall include:

(1) Immediate notification to the complainant of the right to contact the Department regarding the grievance. The plan shall expedite its review of the grievance when the complainant, an authorized representative, or treating physician provides notice to the plan. Notice need not be in writing, but may be accomplished by a documented telephone call.

(2) A written statement to the Department and the complainant on the disposition or pending status of the urgent grievance within three (3) calendar days of receipt of the grievance by the Plan.

(3) Consideration by the plan of the enrollee's medical condition when determining the response time.

(4) No requirement that the enrollee participate in the plan's grievance process prior to applying to the Department for review of the urgent grievance.

(b) Each plan's grievance system shall allow for the Department to contact the plan regarding urgent grievances 24 hours a day, 7 days a week. During normal work hours, the plan shall respond to the Department within 30 minutes after initial contact from the Department.

During non-work hours, the plan shall respond to the Department within 1 hour after initial contact from the Department.

(1) The system established by the plan shall provide for the availability of a plan representative with authority on the plan's behalf to resolve urgent grievances and authorize the provision of health care services covered under the enrollee's plan contract in a medically appropriate and timely manner. Such authority shall include making financial decisions for expenditure of funds on behalf of the plan without first having to obtain approval from supervisors or other superiors within the plan. Nothing in this subsection shall restrict the plan representative from consulting with other plan staff on urgent grievances.

(2) Plans shall provide the Department with the following information concerning urgent grievances:

(A) A description of the system established by the plan to resolve urgent grievances. The description shall include the system's provisions for scheduling qualified plan representatives, including back-up plan representatives as necessary, to be available twenty-four (24) hours a day, seven days a week to respond to Department contacts regarding urgent grievances. Provisions for scheduling shall include the names and titles of those plan representatives who will be available under the system, their telephone numbers, and, as applicable, pager numbers, answer service numbers, voice-mail numbers, e-mail addresses, or other means for contact.

(B) A description of how the Department may access the grievance system established by the plan.

(3) If the plan revises the system established pursuant to subsection (b), the plan shall notify the Department at least thirty (30) days in advance of implementing the revisions.

(c) The plan shall notify the Department before changing or modifying any benefit or services that relates to the urgent grievance submitted to the Department pursuant to subsection (b)(1)(A) of section 1368 of the Act if the enrollee or the enrollee's representative objects to the change or modification.

Authority cited: Section 1344, Health & Safety Code; Reference: Sections 1368 and 1368.01, Health & Safety Code.

*Adopt section 1300.70.4*

Section 1300.70.4. Independent Medical Reviews Experimental and Investigational Therapies.

(a) Enrollees of a health care service plan may request an independent medical review pursuant to sections 1370.4, 1374.30 through 1374.34 of the Act and section 1300.74.30 of title 28 when the plan has denied a therapy or medical service that would otherwise be

covered based on the plan's determination that the therapy or medical service is experimental or investigational.

(b) At the time of the plan's denial of coverage for experimental or investigational therapy, the plan shall notify the enrollee of the ability to seek independent medical review.

(1) The notification must include, at a minimum, information on the independent medical review process, an application and envelope addressed to the Department, the physician certification form and the Department's toll-free information number.

(2) Pursuant to Health and Safety Code section 1368.03(a), the Department does not require that an enrollee participate in the plan's grievance system prior to seeking independent medical review.

(c) Included with the enrollee's application to the Department for independent medical review shall be a copy of the plan or contracted provider's written denial of the therapy or medical service based on the determination that the therapy or service is experimental or investigational.

(d) A certification from the enrollee's treating physician shall be included with the application for independent medical review. The physician's certification shall be on a form from the Department entitled, "Physician Certification Experimental/ Investigational Denials" (DMHC/ IMR 110-11/27/00), or contain all of the following information:

(1) The enrollee has a condition as defined in Health and Safety Code section 1370.4(a)(1):

(2) Background information including the name of the enrollee and the health plan; the physician's name, specialty, board certification, address, telephone, and fax number; whether the physician is contracted with the plan; the enrollee's medical condition; and the specific drug, device, procedure, or other therapy recommended or requested for the enrollee's medical condition.

(3) For non-contracting physicians, the certification shall also include the following:

(A) The physician's license, board-certification or board eligibility to practice in the area appropriate to treat the enrollee's condition; and,

(B) Reference to, or copies of, two documents from the medical or scientific literature, specified in section 1370.4(d) of the Act.

(4) The following statement and physician's signature: "I certify that the requested therapy is likely to be more beneficial than any standard therapy. The information provided herein is true and correct;"

(5) Where expedited review is requested the certification shall include a statement that imminent and serious threat to the health of the enrollee exists pursuant to Health and Safety Code section 1374.31, or the proposed therapy would be significantly less effective if not promptly initiated; and

(6) Attachments, including any additional references or copies of medical and/or scientific literature considered relevant to the requested therapy and any other information relevant to the request.

(e) Incomplete applications will not be referred to an independent medical review organization. However, the Department may waive this requirement in exceptional or compelling circumstances where the need for a prompt determination precludes obtaining all information in writing. In cases accepted for an urgent review, the enrollee's physician must certify in writing, at a minimum, that the enrollee has a life-threatening or seriously debilitating condition, as defined in Health and Safety Code section 1370.4(a), that the requested therapy is likely to be more beneficial to the enrollee than any available standard therapy and describe the medical and scientific evidence relied upon in making the recommendation.

Authority cited: Section 1344, Health and Safety Code. Reference: Section 1370.4, Health and Safety Code.